REMARKS

I. Summary of Office Action

Claims 1-8 and 23-38 are pending in the application. The Examiner rejected claims 1-8 and 23-38. Claims 2 and 28 are rejected under 35 U.S.C. 112. Claims 1-8 and 23-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,578,003 to Camarda et. al. [hereinafter "Camarda"] in view of U.S. Patent No. 7,444,291 to Prasad et. al. [hereinafter "Prasad"].

Summary of Applicant's Response

By this response, Applicants have amended claims 1, 7, 23-27, 28, 33 and 35-38. Applicants also submit new claims 39-44. Care has been taken to ensure that no new matter has been introduced by this response

The Examiner's rejections are respectfully traversed below.

For the sake of convenience, Applicants do not always recite in the remarks section of this Amendment, the specific amendments to the claims when combined with the remaining elements that are patentably distinguishable. Rather, Applicants direct the Examiner to the specific claims where clearly the amendments to those claims in combination with the remaining elements are asserted to be patentably distinguishable over the prior art.

Accordingly, Applicants respectfully submit that the combination of elements in each of the independent claims is patentably distinguishable over the prior art. Withdrawal of the rejection is respectfully requested. In addition, Applicants also submit that the dependent claims, when each of

these claims are considered as a whole, patentably distinguish over the prior art. Withdrawal of the rejection for these reasons as well is requested.

II. **Response to Specific Points in Office Action Dated May 13, 2009**

Applicants submit that the combination of elements and/or steps recited in each presently pending claim, when interpreted as a whole, is patentable over the cited references.

35 U.S.C. 112, first paragraph

The Examiner rejected claims 2 and 28 stating that the claims "recite 'summing a total supply of an associated compliance medication prescribed . . .' However, Applicant does not provide a description of such total supply in the respective specification." 5/13/2009 Office Action, Page 2. Applicants respectfully disagree. For example, the present invention teaches "[l]ikewise the compliance medication information is used, for example, to generate a compliance medication score by summing products of regression coefficients for each compliance medication prescribed to the individual with associated medication supply weights." Page 20, 11. 6-16. Furthermore, the present invention teaches "[o]nce the compliance medications have been determined (STEP 156), a compliance medication score for each medication is generated (STEP 160). In this example illustrated in FIG. 1, this score is generated by summing the days supply for each medication . . . ." Page 27, ll. 5-11. Accordingly, the present invention does disclose "summing a total supply of an associated compliance medication" as recited in claims 2 and 28.

Furthermore, the Examiner states that "[c]laims 2 and 28 are ambiguous as they recited medication supply weights which in claim 1 are recited as a data element different from a regression coefficients [sic]; however Applicant's specification describes such weights as the same as the regression coefficients." 5/13/2009 Office Action, Page 2. Applicants respectfully disagree.

As mentioned above, the present invention teaches "[o]nce the compliance medications have been determined (STEP 156), a compliance medication score for each medication is generated (STEP 160). In this example illustrated in FIG. 1, this score is generated by summing the days supply for each medication . . . ." Page 27, ll. 5-11. On the other hand, regression coefficients are associated with chronic condition scores: "[t]he weights **associated with the chronic condition** are generated using information contained in a pharmacy claims database. Specifically, each weight represents the regression coefficient developed using a multiple regression model with pharmaceutical or total cost as the dependent variable and all chronic conditions of interest as independent variables." Page 28, ll. 6-12.

35 U.S.C. § 103(a) Rejections

The Examiner rejected claims 1-8 and 23-38 as being upatentable over Camarda in view of Prasad. For example, the Examiner states that Camarda discloses "(4) generating a compliance medication score by summing products of regression coefficients for each compliance medication prescribed to said individual with associated medication supply weights, or compliance . . . ." 5/13/09 Office Action, Page 4. Applicants respectfully disagree.

In an effort to better define patent utility, independent claim 1, as well as claim 27, has been amended to recite as follows:

> 1. (Currently Amended) A computer implemented method for generating a chronic condition risk index for an individual using said individual's pharmacy claims by a computer system, said method comprising the steps of:
>
> (1) retrieving by the computer system said pharmacy claims from a pharmacy claims database, and processing by the computer system said pharmacy claims to identify any chronic conditions possessed by said individual;
>
> (2) processing by the computer system said pharmacy claims to identify any compliance medications prescribed to said individual;
>
> (3) generating a chronic condition score by summing regression coefficients for each chronic condition possessed by said individual;
>
> (4) generating a compliance medication score by summing products of regression coefficients for each compliance medication prescribed to said individual with associated medication supply weights, or compliance;
>
> (5) generating a modified chronic condition score by multiplying said chronic condition score by an overall chronic condition regression coefficient;
>
> (6) further modifying said modified chronic condition score by subtracting a no-claims weight from said chronic condition score, if said individual has no pharmacy claims; and
>
> (7) generating, by the computer system, said chronic condition risk index by summing said modified chronic condition score and said compliance medication score.

Without conceding that Camarda and/or Prasad disclose any of the claimed limitations, nowhere does Camarda teach, for example summing regression coefficients for compliance medications **prescribed to an individual**. Instead Camarda teaches analyzing medical data with respect to **population clusters**:

> **the processor uses regression analysis to define population clusters** and to model the behavior of population clusters as regards their response to a variety of intervention messages. It may also model of the **behavior of patients in a cluster** as regards compliance in general, without regard to a particular intervention. These models are probability equations, each of which is the sum of the elements, or cross-products of the elements, of data that which have been shown to be predictive of response to a particular message or compliance behavior in general, each multiplied by its relative power to predict or "weight".

Camarda col. 7 ll. 51-62. Thus, Camarda does not have the ability to "[generate] a compliance medication score by summing products of regression coefficients for each compliance medication prescribed to said individual with associated medication supply weights, or compliance."

Furthermore, the Examiner admits that Camarda "does not disclose (3) generating a chronic condition score by summing regression coefficients for each chronic condition possessed by said individual; (5) generating a modified chronic condition score by multiplying said chronic condition score by an overall chronic condition regression coefficient and (6) further modifying said modified chronic condition score by subtracting a no-claims weigh from said chronic condition score, if said individual has no pharmacy claims." 5/13/09 Office Action, Page 4. Instead the Examiner relies on the combination of Camarda with Prasad and states "Prasad discloses calculating a chronic condition score." *Id.* Applicants respectfully disagree.

Nowhere does Prasad disclose generating a modified chronic condition score by multiplying said chronic condition score by an overall chronic condition regression coefficient. Instead, Prasad teaches "a burden of illness score is calculated by **multiplying each CCG class** in the CCG summary file by a weighting factor (e.g., the incremental cost associated with the presence of the particular CCG class). Prasad col. 14 ll. 25-28. Thus, Prasad utilizes a different coefficient for

each class of the CCG classes or medical episode categories. *See* Prasad col 13 ll. 61-64. However, Prasad does not disclose "generating a modified chronic condition score by multiplying said chronic condition score by **an overall chronic condition regression coefficient**" as recited in claims 1 and 27.

Nowhere does Prasad disclose utilizing a no-claims weight in generating a chronic condition score. Instead Prasad teaches "[o]nce each of the pharmacy claims and medical claims has been associated with a CCG class, a CCG summary file is created for each plan member by inserting a summary file is created for each plan by inserting a zero in the file if the medical episode is present in the member. However, Prasad **does not actively provide and utilize a weighting factor associated with no pharmacy claims**. Accordingly, Prasad does not disclose "further modifying said modified chronic condition score by subtracting a no-claims weight from said chronic condition score, if said individual has no pharmacy claims" as recited in claims 1 and 27.

The Examiner admits that neither of the references disclose "(7) generating by said computer system said risk index by summing said modified chronic condition score and said compliance medication score." 5/13/09 Office Action, Page 4. Instead the Examiner takes "Official Notice that generating a risk index was old and well known in the art at the time the invention was made." *Id.* However, Applicants respectfully remind the Examiner that Official Notice without support can not be taken except in those instances where it is "capable of such instant and unquestionable demonstration as to defy dispute." *In Re Ahlert*, 424 F.2d 1088, 1091 (CCPA 1970). *See also In Re Zurko*, 258 F.3d 1379, 1385 ("[T]he Board cannot simply reach conclusions based on its own

understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some **concrete evidence** in the record in support of these findings.")

Accordingly, Applicants respectfully submit that claims independent claims 1 and similar independent claim 27, as well as all dependent claims there from, are in condition for allowance.

The Examiner rejected claim 23 stating that "Camarda recites the computer retrieving patient information comprising patient eligibility data." 5/13/09 Office Action, Page 5. Applicants respectfully disagree. Nothing in Camarda discloses a computer retrieving patient eligibility data. For example, Camarda teaches the database may include "pharmacy, clinical, medical and patient report data." Camarda col. 7 ll. 1 and 2. Pharmacy data is disclosed as:

> the prescription is for medication so the data also includes "pharmacy data," such as the number of pills, the type of pills, the number of days supply, number of refills, etc. Further, the information may include the pharmacy location, and the name and location of the doctor who wrote the prescription. Based on this information, additional information can be obtained from the records of the pharmacy or health care provider. This includes, e.g., other disease states of the same patient, whether this or some other medication prescription was filled previously, whether it was refilled on time, whether the previous prescription or this one requires refills, the days since the last refill, the average days between refills, pharmacy claim data on the patient, such as national drug codes (e.g., NDC), the cost of the medication and the payment plan (all of which may be predictors of compliance).

Camarda col. 6 ll. 29-44. Thus, some patient information is retrieved by the database **regarding the type of medicine prescribed**, however, there is no disclosure of retrieval of "**patient eligibility data** from at lest one of a health insurer database and a pharmacy benefits database" as recited in claim 23.

Furthermore, the Examiner admits that Camarda does not specifically recite generating a risk index responsive to the patient eligibility data. 5/13/09 Office Action, Pages 5 and 6. Instead, the Examiner takes Official Notice "that generating a risk index based on patient data was old and well known in the art at the time the invention was made." *Id.* However, Applicants respectfully remind the Examiner that Official Notice without support can not be taken except in those instances where it is "capable of such instant and unquestionable demonstration as to defy dispute." *In Re Ahlert*, 424 F.2d 1088, 1091 (CCPA 1970). *See also In Re Zurko*, 258 F.3d 1379, 1385 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some **concrete evidence** in the record in support of these findings.") The Examiner rejected claim 35 under the same analysis as claim 23. Therefore, Applicants respectfully submit that claim 35 is allowable in view of at least the arguments set forth herein.

The Examiner rejected claim 24 stating that "Camarda recites determining a clinical case identification with respect to the patient." Applicants respectfully disagree. For example, the present invention teaches "the index may be used for **research** and **actuarial purposes**, such as clinical case identification uses (e.g., disease management programs)." Page 9, ll. 19-21. Nowhere does Camarda disclose use of data for research or actuarial purposes. Instead, as the Examiner notes, Camarda discloses "identif[ying] patients who need to be part of the intervention; the computer generates the intervention (e-mail, letter, etc) and sends it to the patients. 5/13/09 Office Action, Page 6. Claim 36 is also patentable as the Examiner rejected the claim under the same analysis.

The Examiner rejected claim 26 stating "Camarda recites determining whether to generate comparable groups which may have differing rates of chronic illness, and adjusting for factors including at least one adverse and favorable selection in at least one health plans, programs and health-related interventions." 5/13/09 Office Action, Page 7. Applicants respectfully disagree. Nowhere does Camarda teach the ability to generate comparable groups of differing chronic illness rates. Instead Camarda teaches multiple data stores in generating a demographic cluster large enough to **determine patient behavior**:

> If the system has not yet determined which interventions are effective with which demographic clusters of patients as determined in step 36, the system passes through step 37 because it does not have sufficient information to make a model of patient behavior. As a result, the proposed interventions are merely sent to a wide variety of patients in step 38. The results of these interventions on patient behavior as regards compliance with the refill schedule for the prescriptions are collected and become part of the pharmacy data. On a subsequent pass through steps 31-35, there is now sufficient data available for a regression analysis to be performed in step 37 to determine if there are logical clusters of population, based on the demographic information, which respond in a reasonably predictable manner to one proposed intervention as opposed to another.

Camarda col. 10 ll. 9-22. However, the present invention teaches the use of the chronic illness risk index to determine healthcare related cost in **comparable groups not being directly analyzed**:

> Similarly, the index may be used to explain and predict variation in pharmacy-related costs and variation in total healthcare costs or utilization. Further, the index may be used as **a tool in program evaluation to create comparable groups** to adjust for factors such as adverse or favorable selection into healthplans, programs or health-related interventions.

Page 9, ll. 21-25, Page 10, ll. 1 and 2. The Examiner rejected claim 38 under the same analysis for claim 26. Accordingly, Applicants respectfully submit that claim 38 is allowable in view of at least the arguments set forth herein.

Applicant's decision not to address other features in the claims and/or the features of the remaining dependent claims does not constitute an admission that such elements are disclosed by the cited art, but rather a recognition that such features are moot given the Examiner's failure to provide a showing of the features of the corresponding independent claims. Applicant reserves the option to comment on such elements in further prosecution.

New Claims

By this response, claims 39-42 have been added. Care has been taken to ensure that no new matter has been introduced by the addition of such claims. Applicants submit that claims 39-42 are patentable subject matter independently and in view of its dependency on independent claims 1 and 27, which are also in condition for allowance.

CONCLUSION

Applicants respectfully submit that, as described above, the cited prior art does not show or suggest the combination of features recited in the claims. Applicants do not concede that the cited prior art shows any of the elements recited in the claims. However, Applicants have provided specific examples of elements in the claims that are clearly not present in the cited prior art.

Applicants strongly emphasize that one reviewing the prosecution history should not interpret any of the examples Applicants have described herein in connection with distinguishing over the prior art as limiting to those specific features in isolation. Rather, Applicants assert that it is the combination of elements recited in each of the claims, when each claim is interpreted as a whole, which is patentable. Applicants have emphasized certain features in the claims as clearly not present in the cited references, as discussed above. However, Applicants do not concede that other features in the claims are found in the prior art. Rather, for the sake of simplicity, Applicants are providing examples of why the claims described above are distinguishable over the cited prior art.

Applicants wish to clarify for the record, if necessary, that the claims have been amended to expedite prosecution and/or explicitly recite that which is already present within the claims. Moreover, Applicants reserve the right to pursue the original and/or complimentary subject matter recited in the present claims in a continuation application.

Any claims that have been cancelled are hereby cancelled without prejudice or disclaimer, and Applicants reserve the right to further prosecute these claims in continuing applications. In addition, Applicants have attempted to claim all embodiments disclosed in the present application, and no disclaimer of any embodiments is hereby intended by the presently pending claims.

Any narrowing amendments made to the claims in the present Amendment are not to be construed as a surrender of any subject matter between the original claims and the present claims; rather merely Applicants' best attempt at providing one or more definitions of what the Applicants believe to be suitable patent protection. In addition, the present claims provide the intended scope of protection that Applicants are seeking for this application. Therefore, no estoppel should be presumed, and Applicants' claims are intended to include a scope of protection under the Doctrine of Equivalents and/or statutory equivalents, i.e., all equivalents that are substantially the same as the presently claimed invention.

Further, Applicants hereby retract any arguments and/or statements made during prosecution that were rejected by the Examiner during prosecution and/or that were unnecessary to obtain allowance, and only maintain the arguments that persuaded the Examiner with respect to the allowability of the patent claims, as one of ordinary skill would understand from a review of the prosecution history. That is, Applicants specifically retract statements that one of ordinary skill would recognize from reading the file history were not necessary, not used and/or were rejected by the Examiner in allowing the patent application.

Applicants also traverse any "Official Notice," "Design Choice," "Admitted Prior Art" or other alleged prior art that the Examiner purports is well known with respect to the claimed combination of the present invention. Applicants disagree and request the Examiner to provide a prior art reference describing any of these features that the Examiner has not provided a prior art reference or an affidavit under 37 C.F.R. Section 1.104(d)(2) providing details of why it would have been obvious. In the absence of either, Applicants request withdrawal of this rejection for these reasons as well.

For all the reasons advanced above, Applicants respectfully submit that the rejections have been overcome and should be withdrawn.

AUTHORIZATION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 08-0219, under Order No. 0103864.00129US2 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: September 11, 2009

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